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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,445

10/31/2006

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11/05/2009

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EXAMINER

QIAN, CELINE X

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

11/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,445	Applicant(s) KADYK ET AL.	
	Examiner CELINE X. QIAN	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,7 and 11-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6 and 8-10 is/are rejected.
- 7) ☒ Claim(s) 1,2,4,6 and 8-10 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0905, 0808, 0908</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 1-25 are pending in the application.

Election/Restrictions

Applicant's election of Group I, and B (nucleic acid), D (in cell culture), G (using RAC + cell), M (in a nucleic acid expression assay), and N (no additional testing in a RAC deficient model system) components of the invention of Group I in the reply filed on 9/14/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 3, 5, 7, 11, 12-25 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1, 2, 4, 6, 8-10 are currently under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 9/1/05, 8/11/08 and 9/21/08 have been considered by the examiner.

Claim Objections

Claims 1, 2, 4, 6, 8, 9 and 10 are objected to for containing non-elected subject matter. Amending the claims such that they are only directed to elected inventions is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Pepperkok et al (IDS).

Pepperkok et al. disclose a method comprises the step of: providing an assay system comprising a casein kinase (CSNK) nucleic acid, fibroblast cells IMR-90 which expresses CSNK, contacting the assay system with a test agent (the antisense molecules which are small molecule) under conditions whereby, the system provides a reference activity, and detecting a test agent biased activity of the assay system, wherein a difference between the test agent-biased activity and the reference activity identifies the agent as a candidate RAC pathway modulating agent (see page 247, 2nd col., 2nd paragraph, and Table 1). Pepperkok provides an cell proliferation assay system because it measures cell growth (see Table 1 and Figure 3 and legend). Therefore, Pepperkok et al. disclose the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pepperkok et al., in view of Summerton and Weller (Antisense & Nucleic Acid Drug Development, 1997. Vol. 7, pages 187-195).

The teaching of Pepperkok has been discussed above. However, Pepperkok et al. do not teach the nucleic acid modulator is a phosphothioate morpholino oligomer (PMO).

Summerton and Weller teach the design, preparation and properties of PMO, of which is a novel antisense structural type that solves the sequence specificity problem and provides high and predictable activity in cells. Summerton and Weller teach that PMO also exhibit little or no nonantisense activity, afford good water solubility, are immune to nucleases and are designed to have low production costs (see abstract, and 190-193).

It would have been obvious to an ordinary artisan to use PMO to modulate the expression of CSNK in cells expressing CSNK based on the teaching of Summerton and Weller and Pepperkok et al. The ordinary artisan would have been motivated to do so because the advantage of PMO over the old generation of antisense molecule as discussed by Summerton and Weller. The ordinary artisan would also have a reasonable expectation of success to design such PMO for the CSNK gene because Summerton and Weller provided guidance to design and make such PMO. Using a product known in prior art which can improve an prior art known method for predictable result would have been within the capability of an ordinary skill in the art. Therefore, the claimed invention would have been *prima facie* obvious to an ordinary artisan at the time the invention was made.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of “PMO” is rejected because it is unclear what the term is referring to. In other words, this abbreviation can mean different terms in the context of the claimed invention. The specification fails to provide a definition for this term. It would be remedial to spell out the entire word for this abbreviation.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /
Primary Examiner, Art Unit 1636